

intervertebral dowel” lacks antecedent basis. Claim 6 has been amended for clarification and withdrawal of this rejection under 35 U.S.C. § 112 is respectfully requested.

Claims 1, 9, 11 and 18 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Meriwether et al. U.S. Patent No. 6,090,143 (“Meriwether et al.”). The Examiner applies Meriwether et al. as follows:

...Meriwether et al. teach a box cage 110 for intervertebral body fusion which has upper and lower surfaces defining a thickness therebetween and cooperates with a locking screw 132 having threads which project through slots in the upper and lower surfaces of cage 110 to engage the surface of adjacent vertebrae. Windows in the sides of cage 110 would allow for receipt of bone growth inducing factors. A description of the procedure used to implant the cage/screw combination is set forth with reference to Fig. 5 in lines 10-30 of column 5.

(See October 4, 2002 Office Action at pages 2-3.)

Nowhere does Meriwether et al. disclose a two-part intervertebral spacer possessing a first component being of substantially closed structure comprising bone and a second component engagable within the first component having a height greater than the thickness of the first component as presently recited in amended Claim 1. Similarly, nowhere does Meriwether et al. disclose a method of restoring spacing between adjacent vertebrae using a two-part intervertebral spacer having a ring defining a bore, the ring being of substantially closed structure comprising bone, and a locking implant engagable within the bore of the ring as presently recited in amended Claim 18.

Rather, as noted by the Examiner, Fig. 6 of Meriwether et al. discloses an essentially open structure, which it refers to as cage member 110. There simply is no

disclosure in Meriwether et al. that its cage may be a “substantially closed structure” as required by amended Claims 1 and 18. Moreover, there is no disclosure or suggestion in Meriwether et al. that any part of its cage may be made of bone. The only materials disclosed by Meriwether et al. for fabricating the implant described therein are stainless steel, titanium, carbon and alloy composites (see Meriwether et al. specification, column 7, lines 8-17). As one skilled in the art would recognize, there are significant differences between using metal or rigid synthetic materials as implants compared with bone. Specifically, these differences include, but are not limited to, the following:

1. bone from the vertebrae adjacent to an intervertebral implant will grow onto the surface of an implant made of bone, something that will not occur with a metal or synthetic material;
2. an implant made of bone will eventually be replaced by the natural bone tissue from the recipient of the implant and there will be thus less stress-shielding compared with a metal or synthetic implant. Stress shielding refers to the fact that a metal implant will carry stress rather than the adjacent bone, thus the bone in contact with the metal implant will not be as strong in carrying loads or when placed under stress; and
3. should the implant need to be removed for any reason, an implant made of bone will be easier to remove, with less removal of additional vertebral tissue, as the removal of a metal implant will require the removal of additional healthy vertebral tissue.

Even if it were possible to construct the relatively complex, open framework cage of the Meriwether et al. disclosure from bone, the resulting device would be unlikely to withstand the mechanical loads exerted upon it when implanted in an intervertebral space.

Thus, an intervertebral implant made from bone as presently required by amended Claims 1 and 18, having the very useful biological properties of bone tissue and possessing a substantially closed structure so as to provide for high mechanical strength, is a more advantageous arrangement than the Meriwether et al. implant which is an open cage structure fabricated from a material other than bone tissue.

In view of the foregoing, applicants submit that the invention of the amended claims is both novel and nonobvious vis-à-vis Meriwether et al.

The Examiner has rejected Claims 2, 12, 16 and 17 under 35 U.S.C. §103(a) as obvious over Meriwether et al. According to the Examiner,

...Meriwether et al. teach a box cage 110 for intervertebral body fusion which has upper and lower surfaces defining a thickness therebetween and cooperates with a locking screw 132 having threads which project through slots in the upper and lower surfaces of cage 110 to engage the surface of adjacent vertebrae. The screw 132 contains a hollow interior with windows along its outer surfaces which would allow for receipt of bone growth inducing factors. The head of screw 132 is depicted with a cross-point recess for receipt of insertion instrumentation.

It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the cage of Meriwether et al. in a C-shaped configuration since applicant has not disclosed that such shape solves any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a forming edge in the heating portion or clamp.

(October 4, 2002 Office Action at pages 3-4 (citations omitted)).

However, as noted above, there simply is no teaching or suggestion in Meriwether et al. that its cage may be a “substantially closed structure comprising bone” as required

by amended Claims 1 and 12 (Claim 2 depends from independent Claim 1 and Claims 16-17 depend from independent Claim 12; they incorporate all the limitations of their respective base claims). As described in greater detail above, there is similarly no teaching or suggestion in Meriwether et al. of the advantages to be obtained by forming an implant of bone.

As acknowledged by the Examiner, Meriwether et al. does not teach that the first component may be a generally C-shaped ring. In these circumstances, it is incumbent upon the Examiner to make a showing of a suggestion or motivation to modify the teachings of the Meriwether et al. patent. *See, B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582, 37 USPQ2d 1314, 1318 (Fed. Cir. 1996). Without any support whatsoever, the Examiner asserts that it would have been an obvious design choice to utilize a C-shaped configuration. The Examiner has utterly failed to meet his burden of showing how the prior art provides this motivation, as Meriwether et al. provides no suggestion that would motivate one skilled in the art to form its cage as a “substantially closed structure comprising bone”, and it is highly unlikely the relatively complex, open framework cage of Meriwether et al. could be formed of bone in a C-shaped configuration capable of withstanding the mechanical loads exerted upon it when implanted in an intervertebral space.

In view of the above, applicants submit the invention of the amended Claims 1, 9, 11 and 18 is nonobvious over Meriwether et al.

The Examiner has rejected Claims 5-7, 13 and 14 under 35 U.S.C. §103(a) over Meriwether et al. as applied to Claims 1 and 12 and further in view of Boyce et al. U.S.

Patent No. 6,294,041 ("Boyce et al.")).

As acknowledged by the Examiner, Meriwether et al. does not teach that its cage is partially surface demineralized. According to the Examiner, however, Boyce et al. disclose an implant "...between adjacent vertebrae as shown in Fig. 4..." and also "...disclose production of an implant having a fully or partially demineralized outer surface" (See October 4, 2002 Office Action at page 4.)

While Fig. 4 of Boyce et al. discloses an intervertebral implant, nowhere in Boyce et al. or in Meriwether et al. is there any suggestion that these two disclosures may be combined in the manner proposed by the Examiner. As recently noted by the Federal Circuit in *In re Lee*, 61 USPQ2D 1430 (Fed. Cir. 2002), in order to establish obviousness by a combination of references there must be some teaching or motivation to combine the two references. "This factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority. It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to '[use] that which the inventor taught against its teacher.'" *Id.* at 1434 (quoting *W.L. Gore v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983)). Here, there simply is no teaching or suggestion in either Meriwether et al. or Boyce et al. to combine Boyce et al. with Meriwether et al., nor is there any teaching or suggestion in either reference that such a combination would result in an implant having a "substantially closed structure comprising bone" as presently recited in applicants' amended claims.

Moreover, as Claims 5-7 depend from independent Claim 1 and Claims 13-14

depend from independent Claim 12, they incorporate all the limitations of the base claims. Therefore, for the additional reasons noted above with respect to Claims 1 and 12, it is respectfully submitted that the references fail to make obvious Claims 5-7, 13 and 14.

The Examiner has indicated that Claims 3, 4, 8, 10, 15 and 19-21 would be allowable if rewritten in independent form, including all of the limitations of their base claims and any intervening claims. Applicants submit new Claim 24, which corresponds to original Claim 3 in independent form; new Claim 25, which corresponds to original Claim 4; new Claim 26, which corresponds to original Claim 8; new Claim 30, which corresponds to original Claim 10; new Claim 31, which corresponds to original Claim 19 in independent form; new Claim 32, which corresponds to original Claim 20 in independent form; new Claim 33, which corresponds to original Claim 21 in independent form; and new Claim 35, which corresponds to original Claim 15 in independent form. Applicants respectfully submit these and the other newly added claims are in condition for immediate allowance, such action being earnestly solicited for all pending Claims 1-37.

Respectfully submitted,



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AMENDED SPECIFICATION MARKED TO SHOW CHANGES

Please replace the paragraph beginning on the top of page 3 with the following:

--A variety of different types of intervertebral implants have been developed to perform this function including spinal fusion cages, threaded bone dowels and stepped bone dowels. An exemplary implant is disclosed in U.S. Patent Application Serial No. 09/328,242, filed on June 8, 1999 now U.S. Patent No. 6,277,149 and entitled "Ramp-Shaped Intervertebral Implant", the entire disclosure of which is incorporated by reference herein.--

Please replace the text beginning on the top of page 4 with the following:

--element is a threaded dowel configured to engage the threads in the C-shaped element. The locking element has a height or diameter which is greater than the thickness of the spacer ring such that when the locking element is threaded into the spacer ring [and] , the outer surface of the locking element extends beyond the upper and lower surfaces of the spacer ring so as to engage adjacent vertebral endplates. Preferably, the locking element includes a throughbore for receipt of bone growth inducing materials. Additionally, the locking element may be provided with a bore in its proximal end along with a cross slot for receipt of a suitable insertion instrumentation.--



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AMENDED CLAIMS MARKED TO SHOW CHANGES

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1. (Amended) A two-part intervertebral spacer comprising:

a first component having upper and lower vertebral engaging surfaces and a thickness between the upper and lower surfaces, the first component being of substantially closed structure comprising bone; and,

a second component engagable within the first component and having a height greater than the thickness of the first component.

5. (Amended) The intervertebral spacer as recited in Claim 1, wherein [at least one of] the [first component and] second component [is formed from] comprises a biocompatible material selected from the group consisting of bone, ceramics, polymers, composites, stainless steel and titanium.

6. (Amended) The intervertebral [dowel] spacer as recited in Claim 5, wherein the first component is formed from bone and is partially demineralized to leave a mineralized core of the first component to provide sufficient support to provide subsidence.

12. (Amended) A two-part intervertebral spacer comprising:

a generally C-shaped ring defining a [throughbore] bore and having a predetermined thickness between an upper and a lower vertebral engaging surface, the ring being of substantially closed structure comprising bone; and,

a threaded dowel having a diameter greater than the predetermined thickness of and engagable within, the C-shaped ring.

13. (Amended) The intervertebral spacer as recited in Claim 12, wherein [at least one of] the [C-shaped ring and] threaded dowel [are formed of] comprises a biocompatible material selected from the group consisting of bone, ceramics, polymers, composites, stainless steel and titanium.

18. (Amended) A method of restoring spacing between adjacent vertebrae comprising:

providing a two-part intervertebral spacer having a ring defining a bore and upper and lower vertebral engaging surfaces defining a thickness between the upper and lower surfaces, the ring being of substantially closed structure comprising bone, and a locking implant engagable within the bore of the ring and having a height greater than the thickness of the ring;

positioning the ring within an excised disk space between adjacent vertebrae; and
engaging the locking implant within the ring and with the adjacent vertebrae.